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FEB 11 2004

November 03, 2003

SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, Linvatec Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for the Linvatec 10k Irrigation System 510(k) Number _____.

A. Submitter

Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908
Registration Number: 1017294

B. Company Contact

Laura D. Krejci, RAC
Manager, Regulatory Affairs
(727) 399-5234 Telephone
(727) 399-5264 FAX

C. Device Name

Trade Name:	Linvatec 10k Irrigation System
Common Name:	Irrigation System
Classification Names:	Arthroscope, 888.1100 Endoscope and Accessories, 876.1500
Proposed Class/Device:	Class II
Product Code:	HRX, GCJ

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Summary of Safety and Effectiveness
10K Irrigation System
510(k) # _____
November 03, 2003

D. Predicate/Legally Marketed Devices

Apex Universal Irrigation System 510(k) # K961590
Linvatec Corporation

Hydro-Flex Li
Laparoscopic Irrigation System: 510(K) # K961224
Davol Incorporated

E. Device Description

The Linvatec 10k Irrigation System is a peristaltic, microprocessor controlled pump system designed to provide liquid distention and irrigation during arthroscopic and laparoscopic procedures. The pump is used in conjunction with specific tubing sets designed for either arthroscopic or laparoscopic procedures.

F. Intended Use

The Linvatec 10k Irrigation System provides controlled fluid distension and irrigation to the operative site during arthroscopic and laparoscopic procedures.

G. Substantial Equivalence

The Linvatec 10k Irrigation System is similar in intended use, design and technological characteristics as the Apex® Universal Irrigation System (Linvatec Corporation) and Hydro-Flex Li Laparoscopic Irrigation System (Davol Incorporated). Testing has been conducted to assure the differences in the new device and the predicate devices do not raise any new issues of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2004

Ms. Laura D. Krejci, RAC
Manager, Regulatory Affairs
Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

Re: K033573
Trade/Device Name: Linvatec 10k Irrigation System
Regulation Number: 21 CFR 888.1100, 21 CFR 876.1500
Regulation Name: Arthroscope, Endoscope and accessories
Regulatory Class: II
Product Code: HRX, GCJ
Dated: November 3, 2003
Received: November 13, 2003

Dear Ms. Krejci:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

November 03, 2003

510(k) Number (if known): K033573

Device Name: Linvatec 10k Irrigation System

Indications for Use:

The Linvatec 10k Irrigation System provides controlled fluid distension and irrigation to the operative site during arthroscopic and laparoscopic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE If NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033573